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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,119	05/16/2006	Charles R Cantor	701586-054202US	7233
7590 Ronald I Eisenstein Nixon Peabody 100 Summer Street Boston, MA 02110-2131			EXAMINER YU, MISOOK	
			ART UNIT 1642	PAPER NUMBER
			MAIL DATE 02/10/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/575,119

Applicant(s)

CANTOR ET AL.

Examiner

MISOOK YU

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-17 are pending and under consideration.

Claim Rejections - 35 USC § 102, Maintained

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 16 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by
US-PAT-NO: 6,927,028 (filing date of 08/31/2001)

Claims 16 and 17 are drawn to a method of diagnosing fetal chromosomal abnormality comprising the steps of: a) obtaining a plasma sample from a pregnant female; b) selectively treating said plasma sample to enrich the sample for at least one fetal nucleic acid region; c) determining the paternal or maternal allele frequency using at least one polymorphic marker adjacent to or within the at least one fetal nucleic acid region in the sample of step (b); and d) comparing the paternal or maternal allele frequency of step (c) to a control DNA sample, wherein a difference in allele frequency from other than 50% of paternal and 50% of maternal allele is indicative of a chromosomal abnormality.

Applicant argues the Lo patent fails to teach the enriching step. This argument has been fully considered but found unpersuasive because the Lo patent (note Fig. 4)

teaches bisulfite treatment to the plasma sample from a pregnant woman and this step is considered as same as enriching fetal nucleic acids region in the plasma sample since this step removes (converts methylated cytosine to uracil) the maternal DNA, thus enriching unmethylated fetal DNA intact.

Claim Rejections - 35 USC § 103, Maintained

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US-PAT-NO: 6927028 as applied to claims 16 and 17 above, and further in view of US-PAT-NO: 7348139.

Applicant argues that the Office's interpretation of the claimed invention is not quite right because claim 1 step b) reads "digesting DNA from said plasma sample with an enzyme that selectively and substantially completely digests the maternal DNA to obtain a DNA sample enriched for fetal DNA region". Applicant argues that nothing in the Lo teaches a step of reducing or destroying the maternal DNA to enrich the fetal DNA in the maternal sample.

These arguments have been fully considered but found unpersuasive because the bisulfite treatment to the maternal plasma as taught by the Lo patent in order to remove the maternal DNA is considered same as selectively and substantially completely remove maternal DNA. The Lo patent teaches fetal epigenetic markers (i.e.

differential in differential DNA methylation between fetus and mother) can be detected using the art-known method involving sodium bisulfite and a methylation-specific polymerase chain reaction. The Lo patent teaches treating the maternal plasma with bisulfite selectively and substantially completely remove the maternal DNA leaving the sample for detection of fetal DNA structure.

Applicant argues that all Herman patent teaches is that methylation can be detected with methylation sensitive enzyme but does not teach a step to enrich maternal step using the enzyme.

This argument has been fully considered but found unpersuasive because the phrase "enriching fetal DNA regions in the plasma sample" is same adding bisulfite to the plasma in Lo patent. US-PAT-NO: 6927028 does not teach a methyl-sensitive enzyme that digests only maternal DNA. However, US-PAT-NO: 7348139 (date filed on April 15, 2002) teaches enzymes that digest methylated maternal DNA, leaving unmethylated DNA alone.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MISOOK YU
Primary Examiner
Art Unit 1642

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